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J. Bitt

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

APPLICANT: Connell et al. DOCKET: ALT-5604D CONT II of DIV III  
SERIAL NO: 09/711,240 ART UNIT: 1723  
FILED: November 13, 2000 EXAMINER: J. Drodge  
INVENTION: "METHOD AND APPARATUS FOR KIDNEY DIALYSIS"

Assistant Commissioner for Patents

Washington, D.C. 20231

SIR:

In accordance with the provisions of 37 C.F.R. 1.56 and the requirements of 37 C.F.R. 1.98, Applicants respectfully request that a citation and examination of the documents identified below and on the attached PTO 1449 form be made during the course of examination of the above-identified application for United States Patent.

The documents identified in this statement relate to oppositions submitted by B. Braun Melsungen and Fresenius Medical Care against European Patent No. 0 668 793 B1. This European patent claims priority from U.S. Patent Application Serial No. 975,523 (now U.S. Patent No. 5,326,476) which claims priority from U.S. Patent Application Serial No. 688,174 (now U.S. Patent No. 5,247,434) as does the above-identified patent application. The opposition documents were received by European patent counsel, it is believed, on January 10, 2001 and January 18, 2001 respectively. Applicants are submitting what they believe are the entire set of documents as received by Applicants' European counsel. Applicants are also submitting what they believe to be translations of certain of the documents that are not in English. To the extent

the Patent Office requires any additional information or has any questions regarding this matter, Applicants respectfully request that the Patent Office contact Applicants' undersigned attorney.

## DOCUMENTS

Communication of a Notice of Opposition from the European Patent Office dated January 5, 2001.

Objection on behalf of B. Braun Melsungen AB to Patent 0 668 793 B1 by von Kreisler et al. Patent Attorneys dated January 2, 2001 (with translation).

U.S. Patent No. 4,898,578 to Rubalcaba, Jr. issued on February 6, 1990.

CMS 08 Handbook dated August 4, 1988, published by Fresenius AG (with translation).

Communication of a Notice of Opposition from the European Patent Office dated January 16, 2001.

Objection to European Patent EP - 0 668 793 B1 by Luderschmidt et al. Patent Attorneys on behalf of Fresenius Medical Care dated January 4, 2001 (with translation).

Einspruch gegen ein europäisches Patent (6 pages).

U.S. Patent No. 4,898,578 to Rubalcaba, Jr. issued on February 6, 1990.

CMS 08 Handbook dated August 4, 1988, published by Fresenius AG.

Computer Modelling System 08, CMS 08 document, published by Fresenius AG.

Dialysis System A2008 C document published by Fresenius AG.

Erben, J. et al., "Computer-Supported Risk Analysis of Haemodialysis Patients in Combination with Possible Therapies by the CMS 08," Improvements in Dialysis Therapy, 1989, Vol. 74, page 165. \*

Stefoni, S. et al., "The CMS 08 Modulated Dialysis," Improvements in Dialysis Therapy, 1989, Vol. 74, page 221. \*

Perrone, B., "Evidence of Fluid Shifts during Dialysis Sessions with Sodium and Ultrafiltration Profiles," Improvements in Dialysis Therapy, 1989, Vol. 74, page 191. \*

Deuber, H.J. et al., "Clinical Application of the Sodium Modelling Computation with CMS 08,"  
Improvements in Dialysis Therapy, 1989, Vol. 74, page 159. \*

Eidesstattliche Versicherung (Solemn Declaration) for Raimond Walter dated January 2, 2001  
(with translation).

Copy of photograph labeled Anlage 8.

Programme for European Renal Association XXIXth Congress, 5 pages.

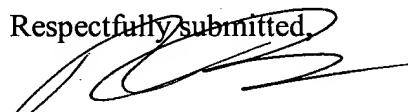
Copy of photograph labeled Anlage 10.

Copy of photograph labeled Anlage 11.

Eidesstattliche Versicherung (Solemn Declaration) for Reiner Spickermann dated December 27,  
2000 (with translation).

\*Applicants are submitting for the Patent Office's convenience a copy of the entire document.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,  


(Reg. No. 30,142)

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SIR:

**CLARIFICATION REGARDING  
INFORMATION DISCLOSURE STATEMENT FILED ON NOVEMBER 13, 2000**

On November 13, 2000, Applicants filed an Information Disclosure Statement. In the Information Disclosure Statement, Applicants cited, *inter alia*, four documents that bore the title "Nephrology Dialysis Transplantation -- Official Publication of the European Dialysis and Transplant Association -- European Renal Association." The purpose of this document, in part, is to clarify that Applicants did not submit the entire publication for each one of those documents. Instead, Applicants submitted what they believe are the relevant portions of the documents.

Specifically, with respect to Volume 2, Applicants submitted the cover page, page A2, two pages of announcements and page 278 that contains abstracts 28-30. Applicants specifically directed the Patent Office's attention to abstract No. 28, entitled "Individual Course of Dialysis with Computer Modeling Dialysis (CMD)."

With respect to Volume 3, Applicants submitted the cover page, page A2, the first page of announcements and two pages, 95 and 96, bearing the heading "Does Better Technology Replace Professional Dialysis Staff?" Applicants note for the record that this article is actually from Aspects of Renal Care 3 (a copy of what appears to be the cover page and table of contents of that document is enclosed).

With respect to Volume 4, Applicants submitted the cover page, page A4, and attached thereto were two documents entitled "Computer Modulated Profile Hemodialysis (CMP-HD) and Vasoactive Hormones" and "Computer-Modulated Profile Hemodialysis (CMP-HD) versus Standard Bicarbonate Hemodialysis (BIC-HD)." These documents, it appears, were erroneously attached to the Volume 4 document. These documents appear to be from New Therapeutic Strategies in Nephrology, Proceedings of the 3<sup>rd</sup> International Meeting on Current Therapy in Nephrology, Sorrento, Italy, May 27-30, 1990. A copy of what appears to be the cover page of that document and the table of contents is enclosed.

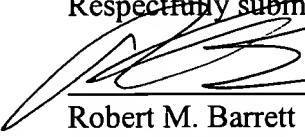
With respect to Volume 5, Applicants submitted the cover page, what appears to be a second page of the document and two articles entitled "Modulated Dialysis: A New Strategy for the Treatment of Intradialytic Intolerance" pp 154-155 and "Computerised Monitoring of Sodium and Fluid During Haemodialysis" pp 162-164.

Applicants also note that the previous Information Disclosure Statement incorrectly identified two documents as "Fresenius, A 2008 D Dialysis System Brochure." One of the documents should have been identified as "Fresenius 2008 B Dialysis System Brochure."

Applicants are submitting a new PTO-1449 Form for all of the references that were filed heretofore for the convenience of the Patent Office. The new PTO-1449 Form should be used instead of the previous PTO-1449 Form.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

 (Reg. No. 30,142)

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